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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)\*

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<sup>\*</sup>The corresponding author has opted to make this information publicly available.

**Date:** Jun 22, 2020

To: "Danielle D Antosh"

From: "The Green Journal" em@greenjournal.org

Subject: Your Submission ONG-20-1225

RE: Manuscript Number ONG-20-1225

Changes in Sexual Activity and Function Following Pelvic Organ Prolapse Surgery: A Systematic Review

#### Dear Dr. Antosh:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

\*\*\*Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Jul 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.\*\*\*

### **REVIEWER COMMENTS:**

Reviewer #1: The authors present a systematic review on sexual fxn after surgery for POP. Given the number of POP procedures done in the US this is a important and germane topic. Overall I found this review to be very well written with a clear and cogent hypothesis and a well done systematic review. Specific comments:

- 1) Is there any data on how the c-section rate effects the rate of POP; it might be nice to add this in the intro or at least discussion.
- 2) Lines 106-108; You used a 10 member panel for your selection of studies. While this in many ways adds credence to your study- does it introduce some bias? Given that the average OBGYN is not an expert would it have been helpful to have a general OBGYN as part of the process? I might comment on this in your discussion.
- 3) Lines 150-152; What instrument (survey, validated?) Was used to evaluate dyspareunia or was it just subjective?
- 4) Lines 186-189- what is is the statistical justification for doing this?
- 5) The results section is quite verbose and difficult to follow- I understand statistically why you have broken up each procedure but there should be a better way to present this in a table.
- 6) The discussion is well written and not over reaching. It is verbose and I would encourage the authors to try to be more succinct in their points.
- 7) A funnel plot representing the I2 would be nice for the primary outcome globally of sexual dysfunction for all procedures to assess heterogeniety.

Reviewer #2: I would like to congratulate the author on a well-executed systemic review and a wonderfully written manuscript. Although I am no expert on systemic reviews, this review seems to comply with all basic requirements. The authors seem to have reviewed and narrowed the selection to a sufficient number of publications to provide for a useful review. Furthermore, the authors define strict inclusion and exclusion criteria resulting in a reliable review based on moderate to high level data. The review is also useful in that its search for data was exhaustive including all languages and time through the advent of PubMed using objective and unbiased computer software to extract data from such publications. All surgery types and corresponding data is independently categorized within the manuscript to make for easy reading and most of the manuscript is concise and efficiently written. Additionally, the authors utilized multiple reviewers for each abstract and allowed for input from all of SGS in the reviews design allowing a level of peer review prior to even initiating the review. My only concern with the manuscript is that the discussion seems to be quite lengthy and wordy. Although I appreciate the author thoroughly describing the benefits and drawbacks to the study, I believe that overall this portion can probably be shortened.

Reviewer #3: This another excellent systematic review by the SGS SRG, this time on sexual activity and POP surgery.

For the most part, I have no questions or concerns. However, there is one issue.

For the categorical data presented, I have no questions.

For the validated questionnaires, I have a question.

How do you know if the statistical significance of the pooled data for the validated questionnaires is clinically significant?

I guess it is reassuring to know that the PISQ scores did not worsen, and at worst showed no difference, but I am skeptical that the PISQ scores had a clinically significant improvement.

One method of determining a clinically significant change in the PISQ-12 scores is based on a change of greater than half the standard deviation of the pre-intervention score. (This approach is based on the recommendations of Sloan and colleagues, who propose this as a conservative estimate of an effect size that is clinically meaningful when using quality of life questionnaires. Sloan JA, Cella D, Hays RD. Clinical significance of patient-reported questionnaire data: another step towards consensus. J Clin Epid, 2005; 58:1217-1219.)

In sexual function articles I have read previously, 1/2 SD would be a change of about 3-4 points typically. I do not know how this applies to a systematic review and data pooling for this.

Anyway, here are your results. native tissue 4.8 Ant repair 3.2 post repair 5.4 USLS 2.9 SPLS 2.9 TVM 0.9 SC 5.3

Please address this in the Discussion.

### STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Tables 1-8, lines 194-196: Several of the entries for consistency had only 2 studies being considered. The I<sup>2</sup> estimate when there are only 2 studies is imprecise and has low power to discern heterogeneity. Those should be either omitted or flagged with a caveat.

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# **EDITOR COMMENTS:**

- 1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
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2 of 4 7/13/2020, 3:38 PM

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page. Meadow Good, Mohammed A Foda, and Rebecca Rogers have not completed the form.

- 3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.
- 4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 25 typed, double-spaced pages (6,250 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.
- 5. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
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- \* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
- 6. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot. The current running title is too long.
- 7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Reviews is 300 words. Please provide a word count.

- 8. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.
- 9. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.
- 10. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table\_checklist.pdf.
- 11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

Remove "Appendix A" and "Appendix B," remove "Table" from each appendix title, and number each appendix item in the way they are ordered in the text. That is, each appendix should be "Appendix 1," Appendix 2," "Appendix 3," etc.

12. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

\* \* \*

If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

- $\hbox{* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf),} and \\$ 
  - \* A point-by-point response to each of the received comments in this letter.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

\*\*\*Again, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by Jul 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.\*\*\*.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965

2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

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July 8, 2020

Dear Editor,

Attached is my revised manuscript: 'Changes in Sexual Activity and Function Following Pelvic Organ Prolapse Surgery.' It is a systematic review on sexual function before and after prolapse surgery registered with PROSPERO (#CRD42019124308). The manuscript follows PRISMA guidelines.

We appreciate the reviewer comments. We have made substantial revisions based on the comments from reviewers and the editor. Please see our responses below. We attached a tracked version of the manuscript in addition to a clean version where changes were accepted.

The abstract word count is 299, and manuscript word count 5,822 (including Tables 1-9). The appendices are excluded from this word count since they have more detailed study data and search terms. We are asking that they are not included in the print but in an online appendix to avoid being over the word count criteria. I have added in Appendix A (search terms) as now Appendix 1 into the main document. Therefore now the search terms are no longer in a separate attachment. Also, Figure 1 from my first submission is the same and did not require any edits, and therefore, it is not attached to the revised document.

All authors listed have contributed to the development of the study and manuscript preparation. As lead author, I affirm that this manuscript is an honest, accurate, and transparent account of the review being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Sincerely,

Danielle Antosh

RESPONSE TO REVIEWER COMMENTS

Varielle antesl

Reviewer #1: The authors present a systematic review on sexual fxn after surgery for POP. Given the number of POP procedures done in the US this is a important and germane topic. Overall I found this review to be very well written with a clear and cogent hypothesis and a well done systematic review. Specific comments:

1) Is there any data on how the c-section rate effects the rate of POP; it might be nice to add this in the intro or at least discussion.

Unfortunately, not all studies report on history of C-section vs vaginal births. Also we did not specifically extract the data on C-section since we are looking at sexual function and not the etiology of the prolapse.

2) Lines 106-108; You used a 10 member panel for your selection of studies. While this in many ways adds credence to your study- does it introduce some bias? Given that the average OBGYN is not an expert would it have been helpful to have a general OBGYN as part of the process? I might comment on this in your discussion.

We don't believe having 10 member review panel introduces bias, as every abstract and paper was double screened and extractions reviewed by 2 members. The SGS SRG involves both FPMRS surgeons and general OBGyn surgeons. Although most of our 10 member group were urogynecologists/FPMRS, there was one general OBGyn involved in data extraction in our group. I added this to line 108.

3) Lines 150-152; What instrument (survey, validated?) Was used to evaluate dyspareunia or was it just subjective?

Although some of the studies reported dyspareunia was defined based on responses to the PISQ-12 questionnaires, most studies either used non-validated measures or did not state if there was one used. We did capture this and took this into account when assigned the Quality of data for each outcome. We also reviewed this in the Discussion section line 440-442.

4) Lines 186-189- what is is the statistical justification for doing this?

We added text to explain the rationale for estimating mean values from reported medians and for using the arcsine transformation. (line 191)

5) The results section is quite verbose and difficult to follow- I understand statistically why you have broken up each procedure but there should be a better way to present this in a table.

We apologize for this, as it is difficult to compile data from so many studies. A more simplified version is also presented in table form. For example, the 'Transvaginal mesh' section for Sexual function outcomes is presented in Table 7. However, the detailed study data is even more detailed in the appendix section. I removed some verbiage from the results section and referred more to the tables.

6) The discussion is well written and not over reaching. It is verbose and I would encourage the authors to try to be more succinct in their points.

Thank you for your comments. We have removed a portion of the Discussion – please refer to tracked changes in the Discussion section.

7) A funnel plot representing the I2 would be nice for the primary outcome globally of sexual dysfunction for all procedures to assess heterogeniety.

We believe the reviewer meant forest, not funnel, plots. We do not think that presentation of the 36 forest plots (one for each presented meta-analysis) would be of value. We had thought that the information in the "Consistency" columns in Tables 2 to 9 (simplified to low, moderate, and high consistency, based on I-squared) was sufficient for the readership of the Green Journal. However, we would be happy to add the actual I-squared values if the editors prefer.

Reviewer #2: I would like to congratulate the author on a well-executed systemic review and a wonderfully written manuscript. Although I am no expert on systemic reviews, this review seems to comply with all basic requirements. The authors seem to have reviewed and narrowed the selection to a sufficient number of publications to provide for a useful review. Furthermore, the authors define strict inclusion and exclusion criteria resulting in a reliable review based on moderate to high level data. The review is also useful in that its search for data was exhaustive including all languages and time through the advent of PubMed using objective and unbiased computer software to extract data from such publications. All surgery types and corresponding data is independently categorized within the

manuscript to make for easy reading and most of the manuscript is concise and efficiently written. Additionally, the authors utilized multiple reviewers for each abstract and allowed for input from all of SGS in the reviews design allowing a level of peer review prior to even initiating the review. My only concern with the manuscript is that the discussion seems to be quite lengthy and wordy. Although I appreciate the author thoroughly describing the benefits and drawbacks to the study, I believe that overall this portion can probably be shortened.

Thank you. We have revised the discussion to cut down on the length. Please refer to the tracked version.

Reviewer #3: This another excellent systematic review by the SGS SRG, this time on sexual activity and POP surgery.

For the most part, I have no questions or concerns. However, there is one issue.

For the categorical data presented, I have no questions.

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Anyway, here are your results. native tissue 4.8
Ant repair 3.2
post repair 5.4
USLS 2.9
SPLS 2.9
TVM 0.9
SC 5.3

Please address this in the Discussion.

We are aware of the use of ½ of the standard deviation of baseline scores to estimate a MID for validated measures and agree that the small changes in PISQ 12 scores observed are unlikely to be highly clinically significant. We also feel that the lack of large changes to scores is reassuring to women and surgeons that the majority of women do not have worsening of sexual function. We have added some further explanation to the discussion, as requested (line 498-501). "Studies did not report on minimally important difference in sexual function scores, and so we must take that into account when interpreting these results. Although most surgery types that showed an improvement in PISQ-12 scores

were statistically significant, there is no established minimally important difference (MID) for the PISQ-12 questionnaire, therefore while changes in PISQ-12 scores may be statistically significant, they might not be clinically significant. Nonetheless, the lack of large changes in sexual function scores in this study is reassuring that women are not experiencing worsening of sexual function."

## STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Tables 1-8, lines 194-196: Several of the entries for consistency had only 2 studies being considered. The  $I^2$  estimate when there are only 2 studies is imprecise and has low power to discern heterogeneity. Those should be either omitted or flagged with a caveat.

We have restricted evaluation of consistency to meta-analyses of at least 3 studies. We have added this to the Methods section and applied changes in the Tables.

Tables 1-8 and lines 213-377 seem to have repetitive entries. Perhaps either a more concise use of text or more consolidation of those Tables would be helpful for the reader. For example, since the Authors have reported prevalence rates of pre and post operative sexual activity by type of tissue repair and stated in Abstract that for some repairs the scores improved, while for others the rates were unchanged, perhaps a summary Table citing sexual function as improved, unchanged etc with all surgical repairs in one Table, then the same format for dyspareunia would be more useful as a summary. The details could then be allocated to either Tables in supplemental digital content or the main text, but not to both.

We have edited to remove some of the repetitive data written in the results section and referred more to the tables. We also agree with the suggestion on a summary table on sexual function changes by surgery type and added this as Table 1.

### **EDITOR COMMENTS:**

- 1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
- A. OPT-IN: Yes, please publish my point-by-point response letter.
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2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page. Meadow Good, Mohammed A Foda, and Rebecca Rogers have not completed the form.

I have emailed the editorial team their updated email addresses and notified the authors to sign this form.

- 3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <a href="https://urldefense.com/v3/">https://urldefense.com/v3/</a> <a href="https://urldefense.com/v3/">https://ur
- 4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 25 typed, double-spaced pages (6,250 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references. Currently the text and tables have 5,822 words however, this does not include the appendices. We request that the appendices be left out of the print and included on an online appendix only, so not to interfere with this word count. Since this is a systematic review, we cannot exclude all the appendix tables on the studies included in the review with their stated quality (bias).
- 5. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
- \* All financial support of the study must be acknowledged.
- \* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- \* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
- 6. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot. The current running title is too long.

7. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

This was reviewed.

In addition, the abstract length should follow journal guidelines. The word limit for Reviews is 300 words. Please provide a word count.

The Abstract is 299 words.

- 8. Only standard abbreviations and acronyms are allowed. A selected list is available online at <a href="https://urldefense.com/v3/">http://edmgr.ovid.com/ong/accounts/abbreviations.pdf</a>;!!Jm49CwcP98
  <a href="mailto:p83js1EA!s">p83js1EA!s</a> GStBN22eNJQbSJcdg-3SfBz7erEWE6iNMxc06b9X7Zx5MwAYOYGQgQBkP\_44\_VsvxITRY\$.

  Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.
- 9. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

This symbol was removed in the text.

10. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here:

https://urldefense.com/v3/ http://edmgr.ovid.com/ong/accounts/table\_checklist.pdf ;!!Jm49CwcP9 8D83js1EA!s GStBN22eNJQbSJcdg-3SfBz7erEWE6iNMxc06b9X7Zx5MwAYOYGQgQBkP\_44\_VAEUbivI\$. I changed the tables to put a hyphen instead of comma for the confidence interval ranges.

11. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

Remove "Appendix A" and "Appendix B," remove "Table" from each appendix title, and number each appendix item in the way they are ordered in the text. That is, each appendix should be "Appendix 1," Appendix 2," "Appendix 3," etc.

This was done.

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